

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELAN PHARMA INTERNATIONAL
LTD. and FOURNIER LABORATORIES
IRELAND LTD.,

Plaintiffs,

V.

LUPIN LIMITED and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 09-1008 (JAG)

OPINION

GREENAWAY, JR., U.S.C.J.*

This matter comes before this Court on the motion by the plaintiffs, Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. (collectively, “Plaintiffs” or “Elan”), seeking to dismiss the defendants’, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Defendants” or “Lupin”) counterclaims, pursuant to Federal Rule of Civil Procedure 12(b)(6) and to strike certain defenses, pursuant to Federal Rule of Civil Procedure 12(f). (Docket Entry No. 22.) For the reasons set forth below, Elan’s Motion to Dismiss Defendants’ Counterclaims and its Motion to Strike Certain Defenses are denied.

PROCEDURAL HISTORY

These motions concern the alleged failure by Lupin to provide, in their responsive pleading, sufficient factual support for their counterclaims and affirmative defenses.

On March 6, 2009, Elan filed a Complaint which avers that Lupin infringed U.S. Patent Nos. 7,276,249 (“the ’249 patent”) and 7,320,802 (“the ’802 patent”) by filing an Abbreviated

* Sitting by designation on the District Court.

New Drug Application (“ANDA”).¹ (Docket Entry No. 1.) On May 8, 2009, Lupin filed its “Answer, Defenses, and Counterclaims” (“Answer”), and included U.S. Patent No. 6,375,986 (“the ’986 patent”) because the ’986 patent is also listed in FDA’s Orange Book in connection with TRICOR®.² (Docket Entry No. 12.)

In its counterclaims asserting non-infringement of the ’986, ’249 and ’802 patents, Lupin avers that “the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim” of the ’986, ’249 or ’802 patents. (Answer at 13-16). Specifically, Lupin states that the claims of the ’986, ’249, and ’802 patents respectively, are “invalid under one or more provisions of 35 U.S.C. §§ 101 - 105.” (Id.)

On June 12, 2009, Elan filed its “Memorandum in Support of Plaintiffs’ Motion to Dismiss Defendants’ Counterclaims and Strike Certain Defenses”. (Docket Entry No. 22.) Elan argues that Lupin “generically asserted in its defenses and counterclaims that the ’249, ’802 and ’986 patents were invalid under one or more provisions of 35 U.S.C. §§ 101 - 105.” (Memorandum in Support of Plaintiffs’ Motion to Dismiss Defendants’ Counterclaims and to Strike Certain Defenses at 2.) Elan contends that Lupin alleged the counterclaims and affirmative defenses without pleading facts that, if true, would entitle Defendants to relief. (Id. at 1.) Elan moves this Court to dismiss Lupin’s counterclaims and to strike certain affirmative defenses asserted by Lupin.³ (Id.)

¹ Lupin filed ANDA No. 90-856, seeking approval to sell generic copies of TRICOR® 48 mg and 145 mg products (Elan’s patented product).

² Lupin claims that the ’986 patent is also invalid, and that it (the ’986 patent) is not infringed by Defendants’ generic product.

³ Lupin requests leave to file an amended answer, should this Court grant Elan’s motion.

LEGAL STANDARDS

A. Rule 12(b)(6) Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) provides that a party may move to dismiss a claim for relief in any pleading for failure to state a claim upon which relief can be granted.

“Federal Rule of Civil Procedure 8(a)(2) requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal quotations omitted). “[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations. [However,] a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Id. (internal citations omitted). “While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.” Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009). “[A] court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” Id. A court must “draw all reasonable inferences in [the non-movant’s] favor.” See Capogrosso v. Supreme Court of N.J., 588 F.3d 180, 184 (3d Cir. 2009).

“When there are well-pleaded allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement of relief.” Id.; see also Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (articulating a two-part test applicable post-Iqbal wherein factual and legal elements are separated and the district court determines whether a plaintiff has shown a “plausible claim for relief”).

A motion to dismiss for failure to state a claim should be granted only if the party asserting the claim is unable to articulate “enough facts to state a claim to relief that is plausible

on its face.” Twombly, 550 U.S. at 570. “The defendant bears the burden of showing that no claim has been presented.” Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

In reviewing a motion to dismiss for failure to state a claim upon which relief can be granted, a court may consider the allegations of the complaint, as well as documents attached to or specifically referenced in the complaint, and matters of public record. Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998). “Plaintiffs cannot prevent a court from looking at the texts of the documents on which [their] claim is based by failing to attach or explicitly cite them.” In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997). “[A] ‘document *integral to or explicitly relied upon* in the complaint’ may be considered ‘without converting the motion [to dismiss] into one for summary judgment.’” Id. (emphasis in original)

B. Rule 12(f) Motion to Strike

Federal Rule of Civil Procedure 12(f) provides, *inter alia*, that the court may strike from the pleading an insufficient defense or immaterial matter. A motion to strike, pursuant to Rule 12(f), will be granted only where “the insufficiency of the defense is clearly apparent.” Cipollone v. Liggett Group, Inc., 789 F.2d 181, 188 (3d Cir. 1986) (internal quotation omitted); see also In re Gabapentin Patent Litig., 648 F. Supp. 2d 641, 647-48 (D.N.J. 2009) (a court may only strike a defense where that defense “is insufficient at law and it cannot succeed under any circumstances”).

The standard used to evaluate a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is also used to evaluate a motion to strike. See Eisai Co., Ltd. v. Teva Pharm. USA, Inc., 557 F. Supp. 2d 490, 493 (D.N.J. 2008) (“[A] motion to strike an affirmative defense challenges the legal sufficiency of the pleading and is therefore governed by the same standard as a 12(b)(6) motion to dismiss.”). An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances. Id.

Accordingly, to determine whether Defendants' affirmative defenses are insufficient, the Court must accept all factual allegations in the Answer as true, construe the Answer in the light most favorable to Defendants, and determine whether, under any reasonable reading of the pleadings, Defendants may be entitled to relief. Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008).

C. Local Patent Rules for the District of New Jersey

On January 1, 2009, New Jersey adopted Local Patent Rules ("L. Pat. R."), which apply to all civil actions filed in, or transferred to, this Court which allege infringement of a patent in a complaint, counterclaim, cross-claim or third party claim, or which seek a declaratory judgment that a patent is not infringed, is invalid or is unenforceable. L. Pat. R. 1.2. The Local Civil Rules of this Court shall also apply to such actions, except to the extent that they are inconsistent with these Local Patent Rules. Id.

Local Patent Rule 3.1 requires that within 14 days of the initial scheduling conference, the patent holder must serve the alleged infringer a "Disclosure of Asserted Claims and Infringement Contentions", which must contain, *inter alia*:

1. Each claim of each patent in suit that is allegedly infringed including the applicable statutory subsections of 35 U.S.C. § 271 asserted;
2. The identification of defendant's "Accused Instrumentality";
3. A chart identifying where each limitation of each asserted claim is found in each "Accused Instrumentality";
4. Whether the alleged infringement is literal or under the doctrine of equivalents;
5. The priority date to which each asserted claim allegedly is entitled; and
6. The basis for any willful infringement claims.

L. Pat. R. 3.1.

Local Patent Rule 3.3 also requires that 45 days after service of the Disclosure of Asserted Claims and Infringement Contentions, each party opposing a claim of patent infringement, shall serve on all parties its “Invalidity Contentions,” which must contain, *inter alia*, the following information:

1. The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious;
2. Whether each item of prior art anticipates each asserted claim or renders it obvious;
3. A chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, including for each limitation that each party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), and material(s) in each item of prior art that performs the claimed function; and
4. Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.

L. Pat. R. 3.3.

ANALYSIS

These motions raises the issue of how the Supreme Court’s recent pronouncements in Twombly and Iqbal regarding the threshold for pleading sufficient facts to defeat a motion to dismiss apply in ANDA actions. Specifically, these motions raise the question of whether the application of those cases reorders the burdens and obligations of the parties at the pleading stage. Here, Elan posits that Lupin must provide a quantum of facts in its answer that far exceeds the ‘bare and naked assertions’ Lupin, according to Elan, has provided thus far. As such, Elan asserts that Lupin’s counterclaims must be dismissed, and two of Lupin’s defenses must be struck. In this Court’s view, the requirements of ANDA actions, and adherence to our local patent rules, do not mandate the result Elan seeks.

Lupin asserts six counterclaims in its answer – three counterclaims asserting invalidity on each of the three patents at issue, and three counterclaims asserting non-infringement on each of the three patents at issue. Elan moves to dismiss all six counterclaims, and moves to strike two identified affirmative defenses.

Elan contends that Lupin's counterclaims do not meet the pleading requirements because Lupin merely asserts that "the '249,'802 and the '986 patents are invalid under one or more provisions of 35 U.S.C. §§ 101 - 105," without identifying which possible provision(s) would be applicable to its invalidity defense. (Brief in Support of Defendants' Opposition to Motion to Dismiss Counterclaims and Strike Certain Defenses at 2). Lupin responds that its counterclaims and defenses comply with the Rule 8 notice pleading standard, and that there is no need for supplementing the facts through an amended pleading.

Federal Civil Rule 8(a)(2) requires that pleadings contain "a short and plain statement of the claim showing that the pleader is entitled to relief" in order to give the opposing party notice of what the claim is and the grounds upon which it rests. McZeal v. Sprint Nextel Corp., 501 F.3d 1354, 1356 (Fed. Cir. 2007) (quoting Twombly, 127 S. Ct. at 1964). In McZeal, the Federal Circuit considered whether the Supreme Court's decision in Twombly changed the pleading requirements of Rule 8(a) in patent infringement actions, and concluded that it did not. See McZeal, 501 F. 3d at 1357 n.4 ("[t]his does not suggest that Twombly changed the pleading requirement of Federal Rule of Civil Procedure 8"); see also Twombly, 127 S. Ct. at 1974 (Rule 8 does "not require heightened fact pleading of specifics, but only enough facts to state a claim for relief that is plausible on its face").

The Court of Appeals for the Third Circuit has provided detailed and highly instructive guidance as to what type of allegations qualify as sufficient to meet the Rule 8 pleading standard, stating, "a claim requires a complaint with enough factual matter (taken as true) to suggest" the

required element. Cummings v. Henn, Civ. Action No. 09-747, 2009 U.S. Dist. LEXIS 21065 at *3 (D.N.J. March 17, 2009) (quoting Phillips, 515 F.3d at 234 (internal citations omitted)). This “does not impose a probability requirement at the pleading stage,” but rather “calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.” Id.

Lupin’s six counterclaims for non-infringement and invalidity of the three patents adhere to the pleading standard enunciated in Rule 8(a)(2). Elan has full notice of Lupin’s claims of non-infringement and invalidity, and Lupin has stated the grounds for these claims. Based on this assessment, the Phillips standard is met.

More important, it is Elan that has the burden of proof in establishing infringement of the patents at issue. “A party asserting infringement must be able to prove by a preponderance of the evidence that a product meets each and every limitation of the asserted claims either literally or under the doctrine of equivalents.” In re Gabapentin Patent Litig., 393 F. Supp. 2d 278, 290 (D.N.J. 2005).

Elan’s motion to dismiss Lupin’s counterclaims and motion to strike certain affirmative defenses for lack of factual information is without a sound foundation. Lupin’s language in its counterclaims and affirmative defenses mirrors the language Elan employed in its own Complaint. There is no basis for this Court to, on the one hand, allow Elan to plead as it has while, on the other hand, require Lupin, inexplicably, to provide more detailed factual support for its counterclaims and defenses. The notion that Lupin must identify what theories of invalidity it intends to pursue, and the facts supporting such theories at this stage is not plausible.

Additionally, the Local Patent Rules require specificity at a later stage than Elan argues is required, pursuant to Twombly and Iqbal. Both Elan and Lupin will have to disclose their respective theories and the accordant facts in order to comply with Local Patent Rules 3.1 and

3.3.⁴ This motion suggests a factual disclosure that the Federal Circuit does not require, and a disclosure that, if required here, would make Rules 3.1 and 3.3 superfluous.⁵ This Court cannot rule in a manner that undermines logic, the Federal Rules, and the District of New Jersey Local Patent Rules.

Elan suffers no strategic disadvantage from this Court not ordering further factual support for Lupin's counterclaims. Elan's ability to provide the Local Civil Rule 3.1 disclosure is not hampered or inhibited as a result of this ruling. The crux of Twombly and Iqbal is to ensure that the defendant (here, Elan, the counterclaim defendant) has fair notice of what is being pled. Elan has that notice.

Finally, Plaintiff urges this Court to follow and apply the rationale set forth in a District of Nevada case – Duramed Pharmaceuticals v. Watson Laboratories, Civ. Action No. 08-00116, 2008 U.S. Dist. LEXIS 103389 (D. Nev. December 12, 2008). In the first instance, this Court is not obligated to follow a District of Nevada precedent. In Duramed, the court, when addressing a motion to dismiss on grounds similarly argued here, ruled that the motion to dismiss should be granted. In the terse opinion, the court noted that the defendants' counterclaims and affirmative defenses failed to specify the grounds for the invalidity and infringement claims asserted, and that

⁴ The District Court of New Jersey Local Patent Rules are designed to require parties to crystallize their theories of the case early in the litigation. Local Patent Rule 3.1 (Patent Disclosures) requires that a party claiming patent infringement shall serve a "Disclosure of Asserted Claims and Infringement Contentions" on all parties. Within the Disclosure, the party must provide, among other information, each claim of each patent in suit that is allegedly infringed by each opposing party, including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted. L. Pat. R. 3.1(a). Forty-five days after service of the disclosure, each party opposing a claim of patent infringement shall serve on all parties its "Invalidity Contentions", which identifies, among other things, "any grounds of invalidity based on 35 U.S.C. § 101 . . ." L. Pat. R. 3.3(d).

⁵ Lupin also states that the Plaintiffs fail to reveal what additional detail is required to provide Elan with sufficient information to formulate a response. The level of detail Elan seeks from Lupin will be obtained during discovery, as elucidated in the Local Patent Rules.

such deficiencies warranted dismissal. Notably, this ruling lacks sufficient analysis to be helpful to the resolution of the motions before this Court. There is no discussion of the nature and timing of disclosure regarding the facts and theories relevant to ANDA claims. Further, unlike the District of New Jersey, there are no local patent rules in the District of Nevada.⁶ Based on these distinctions, Duramed is not persuasive.

Elan's Motion to Strike

The rationale employed in denying Elan's motion to dismiss Lupin's counterclaims leads to the same conclusion regarding Elan's motion to strike two affirmative defenses.⁷ Lupin's second defense states that "the claims of the '249 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 - 105", while its third defense states that "the claims of the '802 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 - 105." (Answer at 10.) The disclosure requirements of the local patent rules mandate the provision of specific factual and theoretical disclosures by both sides in short order. As noted in the counterclaim discussion above, Elan is put on notice of Lupin's defenses and suffers no strategic disadvantage by not obtaining a more detailed answer. There is no basis to grant Elan's motion to strike at such an early stage of this litigation.⁸

⁶ In the District of Nevada, no local patent rules have been published. District of Nevada Local Rules, <http://www.nvd.uscourts.gov/LocalRules.aspx> (Last visited March 31, 2010).

⁷ Lupin alleges nine separate defenses.

⁸ In its opposition to Plaintiffs' motion, Lupin contends that Elan should have moved for a more definite statement under Federal Rule of Civil Procedure 12(e), before moving to dismiss under Rule 12(b)(6). This argument is without merit. Lupin does not cite to a rule or any case law for this proposition. A Rule 12(e) motion establishes that "[i]f a pleading to which a responsive pleading is permitted is so vague or ambiguous that a party cannot reasonably be required to frame a responsive pleading, the party may move for a more definitive statement before interposing a responsive pleading." Fed. R. Civ. P. 12(e).

These motions are "directed to the rare case where because of the vagueness or ambiguity of the pleading the answering party will not be able to frame a responsive pleading" Schaedler v.

Equally important, this Court cannot determine that these defenses could not succeed as a matter of law or that Lupin is not entitled to relief. The inability to reach this determination is in essence, the death knell of Elan's motion to strike.

CONCLUSION

Based on the foregoing, Plaintiff's motion to dismiss defendant's counterclaims, pursuant to Federal Rule of Civil Procedure 12(b)(6), and Plaintiff's motion to strike certain defenses, pursuant to Federal Rule of Civil Procedure 12(f), are denied, without prejudice. Lupin's motion to amend is denied, as moot.

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREENAWAY, JR., U.S.C.J.
(Sitting by designation on the District Court)

Date: March 31, 2010

Eagle Publications, Inc., 370 F.2d 795, 798 (3d Cir. 1967); see also Pitcavage v. Mastercraft Boat Co., 632 F. Supp. 842, 850 (M.D. Pa. 1985) ([M]otions for more definite statements are not viewed with favor and are to be granted only if the allegations contained in the pleading are so vague that defendant cannot reasonably be expected to frame a response to it.) However, when a Rule 12(b)(6) motion is filed, the sufficiency of a complaint's allegations are tested. Viola v. Village of Throop, Civ. Action No. 06-1930, 2007 U.S. Dist. LEXIS 56181 at *5 (M.D. Pa. August 2, 2007). The issue is whether the facts alleged in the complaint, if true, support a claim upon which relief can be granted. Id. This Court has not identified any requirement under the Federal Rules of Civil Procedure that a party must first move under Rule 12(e) for a more definite statement before moving to dismiss under Rule 12(b)(6).